



*Division of  
Administrative Affairs*

# **MRI Safety Committee**

## **Policy #001**

### **MRI Safety Committee Role and Function**

**Version #1**

**Effective: 09/01/2024**

**Revised: New Document**

1. **PURPOSE:**

The purpose of this policy is to delineate the functions, roles, and responsibilities of the FAU Magnetic Resonance Imaging (MRI) Safety Committee.

2. **POLICY STATEMENT:**

- 2.1. The Florida Atlantic University process for reviewing all research (for human subjects or research animals), teaching, clinical applications, and testing activities involving the use of FAU MRI are reviewed by the Magnetic Resonance Imaging Safety Committee (MRISC). The MRISC is appointed by the Vice President for Administrative Affairs to implement federal, state and institutional policy. The MRISC is the institution's central oversight body for matters relating to the use of FAU MRI for research, teaching, clinical use, and testing activities. The MRISC is authorized to approve, request modifications in order to secure approval, withhold approval, or suspend any activities related to use of FAU MRI for research, teaching, clinical, and/or testing.
- 2.2. In addition to reviewing specific MRI use activities, the MRISC also carries out other mandated functions such as reviewing and approving MRI Facility SOPs, reviewing security breaches and incidents involving the use of FAU MRI, and ensuring MRI Facility adherence to established requirements and the standard of care in the industry. It makes recommendations to the Vice President for Administrative Affairs where necessary regarding any aspect of the MRI Facility program(s), facilities, procedures, or personnel training.
- 2.3. The MRISC is responsible for the review of all activities (regardless of whether the activity is funded or not) that involve the use of FAU MRI in research (human subject or research animal), teaching, clinical use, and testing. All activities reviewed by the MRISC require approval by the MRISC prior to initiation.

3. **CONCEPTS AND DEFINITIONS:**

- 3.1. **FAU MRI** – Any MRI equipment owned and operated by FAU.

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- 3.2. **MRISC** – Magnetic Resonance Imaging (MRI) Safety Committee
  - 3.3. **MRMD** - Magnetic Resonance Medical Director (MRMD), a radiologist or physician who is trained and certified in MRI safety and oversees the clinical aspects of the MRI Safety Program.
  - 3.4. **PI** – A Principal Investigator, the individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project.
  - 3.5. **IACUC** – The Institutional Animal Care and Use Committee, responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals. Its oversight functions include an ongoing assessment of animal care and use.
  - 3.6. **IRB** – The Institutional Review Board (IRB) is responsible for oversight of the use of human subjects in research and to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under FAU.
  - 3.7. **IBC** - The Institutional Biosafety Committee Institutional Biosafety Committee (IBC) has been delegated the authority to set University policy with regard to research with recombinant/synthetic nucleic acid molecules, biological materials, and select agents and toxins. The IBC is responsible for reviewing projects that involve, but are not limited to, recombinant DNA, RNAi, pathogens, human materials and other potentially infectious material, as well as transgenic animals.
  - 3.8. **RSC** – The Radiation Safety Committee (RSC) is delegated the authority to promulgate and administer policies and procedures for the FAU Radiation Safety Program with regard to radiation safety for radioactive material at FAU. The RSC reviews and approves all use of radiation at FAU including research, clinical, and academic applications.
4. RESPONSIBILITIES:
- 4.1. The **Principal Investigator (PI)** will be responsible for:
    - Adhering to all policies and procedures of the MRI Safety Program when carrying out research, teaching, or testing with FAU MRI.
  - 4.2. The **MRISC** will be responsible for:

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- Carrying out the mission and functions of the FAU MRI Safety Program as outlined by policy.

### 4.3. The **MRI Medical Director (MRMD)** will be responsible for:

- Providing medical oversight and ensuring the safety of all FAU MRI operations.
- Consulting with FAU faculty and students regarding study design and conduct prior to and throughout the lifecycle of an MRISC protocol.
- Providing guidance to MRISC members regarding medical and operational requirements, as well as input on logistical and environmental issues as part of MRISC protocol review.
- Reporting adverse medical events, security breaches, and other similar events to the Director, EH&S as soon as possible within 24 hours
- Approving MRISC access to the MRI Suite.

### 4.4. The **Office of Environmental Health and Safety (EH&S)** is responsible for:

- Coordinating the administrative aspects of the MRISC.
- Reporting adverse medical events, security breaches, and other similar events to the MRISC as soon as possible.
- Investigating allegations or instances of non-compliance on behalf of the MRISC.
- Scheduling and coordinating, at least annually, a comprehensive review of the program and MRI facilities, and promptly reporting findings to Vice President for Administrative Affairs in writing and/or verbally if there are urgent findings.
- Maintaining committee records, meeting agendas and minutes, applications and protocols, forms, annual inspection and program review reports, etc. within appropriate timeframes but at a minimum, for 3 years after completion of a protocol.

## 5. PROCEDURES:

- 5.1. The MRISC is **not required to review** activities involving only use of non-FAU MRI facilities.
- 5.2. The MRISC is responsible for the **oversight and review of all** activities involving the use of FAU MRI. *Prior* to any activities being initiated by the PI that involve the use of FAU MRI, MRISC (and other required committees) approvals are required as outlined in all applicable policies.
- 5.3. The MRISC will investigate and evaluate all **concerns** raised by anyone regarding the use of FAU MRI.
- 5.4. The MRISC **may not conduct review** of non-MRI specific elements of the research covered in the scope of other committees such as the IACUC (care and use of animals in research), the IRB (use of human subjects), or the RSC (use of radioactive materials)

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in research.) It is expected that the MRISC approval of a protocol will be required before other university committees may approve the research.

- 5.5. The MRISC will have standing **monthly meetings**. When necessary, the MRISC will convene more often to address urgent issues. A quorum (defined as 1 more than one-half of voting members) of committee members must be present to conduct official business. Committee members may participate in meetings via teleconference and/or videoconference. MRISC members are responsible for reviewing meeting materials ahead of time and being prepared to discuss and finalize protocols at regularly convened meetings. Meeting agendas and review materials are distributed approximately 5 working days prior to the scheduled meeting date. The MRISC will follow the agenda topics at each scheduled committee meeting. Each action will be followed by a motion, a second, and a vote. A majority vote from the quorum present is required to pass a motion. All motions and subsequent votes will be recorded in the minutes. Specific protocol review procedures are referenced in MRISC Protocol and Amendment Review policy.
- 5.6. The MRISC will **review protocols** to ensure, that at a minimum, all proposals include sufficient detail and a completed application of use of MRI.
- 5.7. **MRISC Membership** includes, as a minimum, at least seven (7) voting members including, the MRI Medical Director (Chair), the MRI Physicist, the MRI Technologist, the FAU Radiation Safety Officer, FAU Attending Veterinarian, and other voting members who are experienced in the use and handling of MRI and represent various types of uses of MRI at FAU. Non-voting members will include at a minimum, the Director, EH&S and a representative of the Division of Research. An effort will be made to include membership that represents the diversity of research at FAU. Members may be nominated by college deans, department chairs and colleagues, among others.
- 5.8. MRISC members will receive **training** to Level II – Advanced MRI Safety, at a minimum with a required biennial renewal.
- 5.9. **The Chair** of the MRISC must be a medical doctor with at least one year experience serving on an MRI Safety Committee. This position is integral to the success of the MRI Safety Program and must actively participate in all aspects of the program. They will lead meetings, guide protocol review and discussion, maintain relevant credentialing and certifications required, head non-compliance investigations, communicate directly with researchers, when necessary, participate in annual facility inspections, and meet with the Vice President for Administrative Affairs, deans, chairs, and researchers when needed.
- 5.10. MRISC **members** will conduct an annual review of the MRI Facility(s) including EH&S inspections. MRISC members are expected to participate in the program review and identify areas in need of addressing or improvement.
- 5.11. The MRISC has the authority to **suspend** any activity involving the use of FAU MRI if it finds noncompliance with the FAU MRI Safety Manual, MRI Facility SOPs, or the reasonably accepted standards of care in the industry as defined by the American College of Radiology (ACR). Instances of non-compliance must be appropriately investigated by the MRISC. Suspension may occur only after review of the matter at a convened meeting of a quorum of the MRISC and with the suspension vote of a

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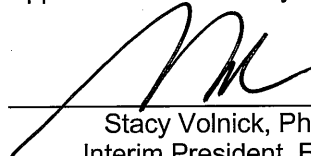
majority of the quorum present. The MRISC must consult with the Vice President for Administrative Affairs regarding the reasons for suspension.

- 5.12. The MRISC will exercise due diligence in avoiding **conflicts of interest (COI)** to assure the integrity of the institution's MRI Safety Program and, as such, will make known any potential or perceived COI concerning all business conducted by the MRISC. MRISC members in any of the following categories could have a COI for a specific protocol under review, or a COI for specific business issues under discussion: 1) Principal Investigator; 2) Co-Investigator, or Sponsor; 3) Investigator receiving funding from the study, as listed in the study budget; 4) In a supervisory role over the PI of the study; 5) Family member of PI; and/or 6) MRISC members listed on the accompanying grant proposal; and/or 7) A financial interest as defined by the DoR Financial Conflict of Interest Policy. Note: Peripheral knowledge or indirect involvement in certain activities may not rise to the level of a COI but might result in member abstention from a vote or discussion.
- 5.13. No MRISC member or EHS Committee Coordinator shall breach the **confidentiality** of the MRISC process by: a) disclosing confidential or proprietary information to any non MRISC member, and b) discussing, disclosing or communicating any details of MRISC business to any third parties without the consent of the MRISC Chair, Director, Environmental Health and Safety, or the Vice President for Administrative Affairs.

### 6. RELATED INFORMATION:

- MAN15 – MRI Safety Manual

Approved and issued by order of:

  
Stacy Volnick, PhD  
Interim President, FAU  
Vice President Administrative Affairs

DATE:

8/21/2024

### POLICY MAINTENANCE SECTION

Last Revision Date	New Document
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Review Frequency	3 years
Version	1
Time-sensitive Items	N/A

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**THIS POLICY RESCINDS ALL OTHER WRITTEN DIRECTIVES REGARDING THIS TOPIC.**

7. RECORD OF CHANGES/STATUS CONTROL:

<b>Version</b>	<b>Date</b>	<b>Summary of Changes</b>	<b>Reviewed By</b>
1	09/01/2024	New Document	<ul style="list-style-type: none"><li>• W. Ash Graves</li><li>• A. Newberg</li><li>• MRISC</li></ul>